K002630

NOV 21 2000

EXHIBIT 2

NidaCon International AB
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Contact: Paul V. Holmes ***MSc, PhD, DrMedSc.***, General Manager

August 22, 2000

510(k) Summary of Safety and Effectiveness

1. Identification of the Device:
   Proprietary-Trade Name: **PureSperm® Wash**
   Classification Name/Product Code: 85 MQL(Cervical Cap per 21 CFR 884.5250)
   Common/Usual Name: Sperm Separation Medium

2. Equivalent legally marketed devices: **SpermRinse -20/-100, K000621.**

3. Indications for Use (intended use) The product is intended to be used as an accessory for the separation and purification of human spermatozoa by density gradient centrifugation of human semen samples, where the prepared sperm are used for IntraUterine Insemination (IUI) (K980814) and for the treatment of involuntary infertility by utilizing one of the Assisted Reproductive Technologies (ART)(K984172).

4. Description of the Device: PureSperm® Wash consists of a buffered salt solution containing glucose, EDTA and human serum albumin. The pH, osmolality and salts of PureSperm® Wash are formulated to be compatible with human sperm following their centrifugal separation and purification. The product is packaged in two bottle sizes, 20 mL and 100 mL sizes. The bottles for sale, being Type I borosilicate glass, are packaged individually in white virgin-fibre cartons. Both the bottles and the cartons have pharmaceutically approved labels showing batch number, production date and expiry date. In addition, every carton contains an insert with a full description of the product, including instructions for use and precautions.

5. Safety and Effectiveness, comparison to predicate devices. The results of clinical trials and comparative testing against predicate product indicates that the new device is as safe and effective as the predicate device.

6. Conclusion: Based on the similarity of composition, product testing results, and intended use, PureSperm® Wash is substantially equivalent to the predicate device named above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 21 2000

NidaCon International AB
c/o Daniel Kamm,P.E.
Kamm & Associates
PO Box 7007
DEERFIELD IL 60015

Re: K002630
PureSperm® Wash
Dated: August 22, 2000
Received: August 23, 2000
Regulatory Class: II
21 CFR §884.6180/Procode: 85 MQL

Dear Mr. Kamm:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

j) Indications for Use

510(k) Number_____

Device Name: ***PureSperm® Wash,*** accessory to Sperm separation medium, Density gradient centrifugation medium

Indications for Use: The product is intended to be used as an accessory for the separation and purification of human spermatozoa by density gradient centrifugation of human semen samples, where the prepared sperm are used for IntraUterine Insemination (IUI) (K980814) and for the treatment of involuntary infertility by utilizing one of the Assisted Reproductive Technologies (ART)(K984172).

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the Counter Use

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K002630